

REMARKS

The present application was filed in the United States from a PCT application under 35 USC § 371. Therefore, the United States Patent Office must apply “unity of invention” standards, and not U.S. restriction standards, to the invention. PCT rule 13.2 stipulates that “the requirement of unity of invention shall be fulfilled only when there is a technical relationship among the inventions involving one or more of the same or corresponding ‘special technical features.’” The expression ‘special technical features’ is defined as “those technical features that define a contribution which each of the inventions, considered as a whole, makes over the prior art.” See Manual of Patent Examining Procedure (MPEP), Appendix A1, Annex B, Part 1(b).

In the present case, a ‘special technical feature’ over the prior art shared by the claims are the protein of claim 1, and the DNA encoding the protein of claim 1. Unity of invention has already been established for the claims of this application. The International Preliminary Examination Report on p. 1 (a copy of which is attached herewith) found unity of invention. The Examiner has not presented sufficient reason to overturn the finding of the International Examining Authority.

The Examiner states that the proteins and encoding nucleotides of Group I are structurally and functionally different chemical compounds from the antibody of Group III and ... the polynucleotides of Group I are also functionally different from the antisense DNA of Group II, each of which can be made and used without the other. Applicants respectfully submit that the antibodies of Group III are defined by the proteins of Group I (they form because of their interaction with the proteins of Group I, without which they would not be known) and the antisense DNA of Group II is defined by the

DNA of Group I, without which the sequence that defines the DNA of Group II would not be known, nor would its function of being “antisense” to the DNA of Group I.

Similarly, the methods of Group III cannot be performed without the proteins of Group I.

In addition, the administrative instructions regarding unity of invention asserts that unity of invention should be considered only in relation to the *independent* claims.

As stated MPEP, Appendix A1, Annex B, Part 1(c)):

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. By “dependent” claims is meant a claim which contains all the features of another claim and is in the same category of claim as that other claim (the expression “category of claim” referring to ...). If the independent claims avoid the prior art and satisfy the requirement of unity of invention, *no problem of lack of unity arises* in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention. (Emphasis added.)

In this context, a dependent claim is defined as a claim which contains all the features of another claim AND is in the same category of invention as that other claim (i.e., product, process, apparatus, etc.). Using this analysis, all the claims of Groups II and III would be deemed “dependent” on claim 1 of Group I because all the claims of Groups II and III require the proteins or DNA of Group I. Therefore, the restriction between Groups I, II and III, at the very least, is fatally flawed and the claims in Groups I, II and III should be examined together.

The Examiner merely points out that there are structural or functional (or both) differences between the product of Groups I, II, and III. This is not the test for unity of invention. The question is “do the claims share the same or corresponding special technical features?” – i.e., features that distinguish the invention from the prior art. In

this case, the protein and DNA defined in Group I are special technical features that help distinguish the invention from the prior art.

Considering Group IV, the proteins and DNA of Group I is a requirement to practice the methods of claims 15 and 17. PCT rule 13.2 does not require, as the Examiner states, “a common utility based upon a common structural feature.” As set forth in MPEP, Appendix A1, Annex B, Part 1(e)(i), unity of invention exists, and the following combinations of claims of different categories is permitted:

“(i) in addition to an independent claim for a given product, an independent claims for a process ... *and* an independent claim for a use of the said product” (emphasis added).

Further, example 6 in MPEP, Appendix A1, Annex B, Part 2, provides independent claim 1 for a fuel burner with properties X (tangential fuel inlets into a mixing chamber), a process for making a fuel burner including the step of forming properties X (claim 2), an apparatus for carrying out a process for making a fuel burner with properties X (claim 4) and a process for manufacturing carbon black including the step of tangentially introducing fuel into properties X of a fuel burner. Claims 2 and 4 are clearly different processes, i.e. uses, involving properties X, but claims 1, 2, 4, and 6 are deemed to have unity of invention because all these claims require properties X. In the present case, claims 15 and 17 of Group IV are different methods, but both require the proteins of Group I to carry out the methods. Therefore, the claims of Group IV are also linked to the claims of Group I by the proteins of Group I (a special technical feature).

As stated above, these features (“protein comprising the amino acid sequence of SEQ ID NO 2 ...” and “DNA encoding the protein of claim 1”) are required by all the claims in Groups II, III and IV. As can be seen,

- the antisense DNA of Group II (claim 7) is against the DNA of claim 3 in Group I;

- the antibody of Group III (claims 12-14 and 16) binds to the protein of claim 1 in Group I.

- the methods of claims Group IV (claims 15 and 17) require the proteins of Group I because both claims 15 and 17 require measuring the proteins of Group I to carry out the methods. Therefore, Groups I-IV related to a single general inventive concept under PCT Rule 13.1 and should be examined as a single group.

CONCLUSION

The restriction of Groups I, II, III and IV is in error and they should be examined together because groups I, II, III and IV are linked by the “special technical features” of the protein in claim 1 – “a protein comprising the amino acid sequence of SEQ ID NO 2”, and the DNA of claim 3 – “A DNA encoding the protein of claim 1.” See claims 1 and 3, respectively. Claim 7 of Group II is linked to claim 3 and thus to claim 1 because the antisense DNA of claim 7 is that which is against the DNA of claim 4 (which codes for the protein of claim 1). The antibody of Group III in claims 12-14 binds to the protein of claim 1 and is thus linked to Group I. In Group IV, the “immunoassay method for measuring” of claim 15 and the “method for detecting mesangial proliferative nephropathy” of claim 17 both require the protein of claim 2 (dependent on claim 1) for the method and are thereby linked to Group I.

For those reasons, Applicants provisionally elect Group I with traverse with respect to Groups II, III and IV. It is believed that all pending claims are in condition for allowance and so reconsideration of the claims and a notice of allowance are therefore requested.

Applicants hereby petition for a one-month extension of time and request that the amount of \$110 be charged to deposit account number 19-4972, as well as any additional fees that may be required for the timely consideration of this application. The Examiner is requested to telephone the undersigned if any matters remain outstanding so that they may be resolved expeditiously.

Date: November 17, 2003

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Barbara J. Carter". The signature is fluid and cursive, with the first name "Barbara" and last name "Carter" clearly distinguishable.

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